Application Serial No.: 10/658,932

Filed: September 9, 2003

Page 2 of 14

This listing of the claims replaces all prior versions in the application.

Listing of Claims:

1. (Currently Amended) An implantable prosthesis of shape generally similar to that

of a spinal intervertebral disc, comprised of a biocompatible elastomer with a compressive

modulus of mechanical elasticity less than about 100 megaPascals, with an ultimate strength

in tension generally greater than about 100 kiloPascals, that exhibits the flexibility to allow at

least 2 degrees of rotation between the top and bottom faces with torsions of at least about

greater than 0.01 N-m without failing.

2. (Currently Amended) A prosthesis according to Claim 1 wherein the device has an

ultimate compressive strength sufficient to withstand a compressive load greater than 1

MegaPascals.

3. (Currently Amended) A prosthesis according to Claim 1 wherein the material used

for the device has an a mechanical ultimate strength in tension greater than about 5 MPa.

4. (Original) A prosthesis according to Claim 1 wherein the device is made of a single

solid elastomeric material.

5. (Currently Amended) A prosthesis according to Claim 1 wherein the elastomer has

a compressive modulus of mechanical elasticity greater than 1.0 MPa.

6. (Currently Amended) A prosthesis according to Claim 1 wherein the elastomer has

a compressive modulus of mechanical elasticity less than 20 MPa.

Application Serial No.: 10/658,932

Filed: September 9, 2003

Page 3 of 14

7. (Currently Amended) A prosthesis according to Claim 1 wherein the device has a compressive modulus of mechanical elasticity less than about 10 MPa and greater than about

200 KPa.

8. (Currently Amended) A prosthesis according to Claim 1 wherein the elastomer has

a <u>compressive modulus of mechanical</u> elasticity that is not constant.

9. (Original) A prosthesis according to Claim 1 wherein the delivered size of the

prosthesis can expand at least 5% in at least one dimension over one day, in saline.

10. (Original) A prosthesis according to Claim 1 wherein the delivered size of the

prosthesis can expand at least 50% in at least one dimension in vivo without injection of

material.

11. (Currently Amended) A prosthesis according to Claim 1 wherein the delivered

size of the prosthesis can expand at least 20% over one day in at least one dimension in vivo

and can generate a cranial-caudal force of greater than about 1 Newton.

12. (Original) A prosthesis according to Claim 1 wherein the delivered size of the

prosthesis can expand at least 100% by a combination of springs and elastomeric

components.

13. (Currently Amended) A prosthesis according to Claim 1 the elastomer defines an

exposed surface that is further modified to provide specific surface characteristics.

14. (Original) A prosthesis according to Claim 13 wherein the surface characteristics

are physically or biochemically modified to provide enhanced adhesion to a vertebral body.

10/650

Application Serial No.: 10/658,932

Filed: September 9, 2003

Page 4 of 14

15. (Currently Amended) A prosthesis according to Claim 13 wherein the surface

includes, in part, a fabric.

16. (Currently Amended) A prosthesis according to Claim 13 wherein the surface

includes, in part, a metal solid or mesh.

17. (Currently Amended) A prosthesis according to Claim 13 wherein the surface

includes, in part, a porous structure with undercuts.

18. (Currently Amended) A prosthesis according to Claim 13 wherein the surface

includes, in part, a rough surface greater than 5 nanometers.

19. (Currently Amended) A prosthesis according to Claim 13 wherein the surface

includes, in part, a bioactive molecule.

20. (Currently Amended) A prosthesis according to Claim 1 wherein the surface

characteristics of the prosthesis <u>allow</u> are modified to provide cellular ingrowth.

21. (Currently Amended) A prosthesis according to Claim 1 wherein the surface

characteristics of the elastomer are biochemically modified to provide enhanced water

transport.

22. (Currently Amended) A prosthesis according to Claim 1 wherein the surface

characteristics of the prosthesis are physically modified to provide enhanced chemical

transport.

23. (Currently Amended) A prosthesis according to Claim 1 wherein the device is a

unitary non-articulating plateless body made of a single solid elastomer with a compressive

Application Serial No.: 10/658,932

Filed: September 9, 2003

Page 5 of 14

modulus of elasticity between about 0.2 and [[5]] 10 megaPascals with tab extensions for fixation to the adjacent vertebral bodies.

24. (Original) A prosthesis according to Claim 1 wherein the disc is composed of a material that contains a ring of continuous fiber.

25. (Currently Amended) A prosthesis according to Claim 1 that contains appendages to allow for physical attachment to the vertebral body and to prevent dislodgement of part in situ.

26. (Original) A prosthesis according to Claim 1 wherein the material is a cryogel.

27. (Original) A prosthesis according to Claim 1 wherein the material is a composite material composed of more than one substance.

28. (Original) A prosthesis according to Claim 1 that is a permanent implantable medical device.

29. (Currently Amended) A sterile prosthesis according to Claim 1 wherein the body is manufactured as an oval or kidney shape for use as a spinal disc prosthesis that substantially corresponds to a shape of a human spinal disc, expands at least about 20% in height when placed in [[n]]Normal saline solutions, has exposed fibers on the cranial and caudal surfaces, has a unitary non-articulating solid body, with the composed of a biocompatible elastomer having a compressive modulus of elasticity between about 1.5MPa and about 10 MPa, an ultimate compressive strength greater than about 1 MPa, an ultimate tensile stretch greater than about 25% in at least one direction, and comprises eontains fabric extensions from the body for attachment to the sides of a the vertebrae.

30-33. (Canceled)

Application Serial No.: 10/658,932

Filed: September 9, 2003

Page 6 of 14

34. (Currently Amended) An implantable spinal disc body having a superior surface and an inferior surface joined by a circumferential surface comprised of a biocompatible elastomer with a compressive modulus of mechanical-elasticity less than about 100 megaPascals and an ultimate strength in tension greater than about 100 kiloPascals.

- 35. (Currently Amended) The implantable spinal disc body of claim 34 wherein the implantable spinal disc superior and inferior surfaces are substantially that of a kidney corresponding to a human spinal intervertebral disc shape, shaped and formed by an extended oval surface and an indented surface, and wherein the cross-section of the implantable spinal disc is substantially rectangular.
- 36. (Original) The implantable spinal disc body of claim 34, wherein the periphery of the superior and inferior surfaces is substantially flat.
- 37. (Original) The implantable spinal disc body of claim 34, wherein the superior and inferior surfaces have a roughness index of between about 1 nm and about 2 mm in height.
- 38. (Original) The implantable spinal disc body of claim 37, wherein the circumferential surface has a roughness index of less than 1 mm.
- 39. (Original) The implantable spinal disc body of claim 34, wherein the implantable spinal disc body is at least partially surrounded by an attachment extension member having a plurality of superior and inferior tabs connected to a band member for attachment of the implantable spinal disc to adjacent superior and inferior vertebral surfaces, respectively.
- 40. (Currently Amended) The implantable spinal disc body of claim 34, wherein the superior and inferior surfaces are covered with a surface treatment to promote attachment to the adjacent vertebral bodies, and wherein the disc body is a plateless unitary body defined by a freeze-thaw hydrogel.

Application Serial No.: 10/658,932

Filed: September 9, 2003

Page 7 of 14

41. (Original) The implantable spinal disc body of claim 34, wherein the superior and inferior surfaces are provided with a plurality of pores to promote tissue ingrowth.

- 42. (Currently Amended) The implantable spinal disc body of claim 34 wherein an [[the]] anterior portion of the implantable spinal disc body is of greater thickness than a [[the]] posterior portion.
- 43. (Currently Amended) An implantable spinal disc body of a biocompatible elastomer material having a mechanical compressive modulus of elasticity that is less than about 100 megaPascals and an ultimate strength in tension greater than about 100 kiloPascals, the body comprising:

a substantially concave superior surface having a substantially flat periphery surface; a substantially convex inferior surface having substantially flat periphery; the superior and inferior surfaces being joined by a circumferential surface; and the implantable spinal disc body being further characterized as being of a kidney shape formed by an extended oval surface and an indented portion, having a substantially rectangular cross-section, and having an anterior portion of greater thickness than [[the]] a posterior portion.

- 44. (Original) The implantable spinal disc body of claim 43 wherein the superior and inferior surfaces have a roughness index of between about 1 nm and about 2 mm in height and the circumferential surface has a roughness index of less than 1 mm.
- 45. (Original) The implantable spinal disc body of claim 43 further comprising: an attachment extension band member at least partially surrounding the circumferential surface of the implantable spinal disc body; and

Application Serial No.: 10/658,932

Filed: September 9, 2003

Page 8 of 14

a plurality of superior and inferior tabs extending from said attachment extension band member for attachment of the implantable spinal disc body to adjacent superior and inferior vertebral surfaces, respectively.

- 46. (New) A prosthesis according to Claim 4, wherein the device is a plateless nonarticulating unitary body.
- 47. (New) The implantable spinal disc according to Claim 43, wherein the device has a non-articulating passively expandable unitary body of freeze-thaw cryogel that defines a core and annulus of the spinal disc implant.
- 48. (New) An implantable spinal disc having a flexible unitary non-articulating solid body, the unitary body having a nucleus and annulus that are both defined by a crystalline PVA hydrogel, the unitary body having a shape generally similar to that of a human spinal intervertebral disc, wherein the crystalline PVA hydrogel has a compressive modulus of elasticity that is between about 1 MegaPascal to about 20 MegaPascals, and an ultimate tensile and compressive strength of at least about 100 kiloPascals.
- 49. (New) A disc according to Claim 48, further comprising a mesh ring attached to an axially extending circumferential surface of the unitary body.
- 50. (New) A disc according to Claim 48, wherein the mesh ring comprises a mesh fabric.
- 51. (New) A disc according to Claim 48, further comprising a porous material attached to superior (top) and inferior (bottom) surfaces of the unitary body to allow for tissue ingrowth from adjacent vertebral tissue in situ.
 - 52. (New) A disc according to Claim 48, wherein the unitary body is configured to

Application Serial No.: 10/658,932

Filed: September 9, 2003

Page 9 of 14

passively axially expand in situ by at least about 10% over time.

53. (New) A disc according to Claim 48, wherein the unitary body is configured to passively axially expand *in situ* between about 20% to about 40% over at least about 24 hours.

54. (New) A disc according to Claim 53, wherein the unitary body is configured to expand in height *ex vivo* about 50% over about 24 hours when placed in a bath of Normal saline.

55. (New) A disc according to Claim 48, wherein the unitary body has anisotropic elasticity.

56. (New) A disc according to Claim 48, wherein the unitary body has substantially the same durometer for locations proximate the nucleus and the annulus.

57. (New) A disc according to Claim 48, further comprising at least one inferior tab and at least one superior tab extending from the unitary body.

58. (New) A disc according to Claim 52, further comprising a polyester fabric attached to the upper and lower surfaces of the unitary body.

59. (New) A disc according to Claim 48, wherein the crystalline PVA hydrogel is devoid of structural reinforcement and is defined by a freeze-thaw PVA hydrogel.

60. (New) A disc according to Claim 48, wherein the unitary body has a compressive modulus of elasticity of about 10 MPa, and an ultimate strength in tension and compression of a least about 1 MPa to thereby provide a relatively compliant body that has sufficient elasticity to allow flexible motion between vertebrae and act as a mechanical shock absorber.

Application Serial No.: 10/658,932

Filed: September 9, 2003

Page 10 of 14

61. (New) A disc according to Claim 60, wherein the unitary body has a mechanical

ultimate strength in compression of at least about 10 MPa.

62. (New) A disc according to Claim 48, wherein the unitary body has opposing top

and bottom faces, and wherein the unitary body can withstand between about 2-10 degrees of

rotation between the top and bottom faces with torsions of between about 0.1 N-m to about 1

N-m.

63. (New) A spinal disc prosthesis having a solid unitary body consisting essentially

of a non-reinforced freeze-thaw PVA cryogel that defines a core and annulus, wherein the

body has a compressive modulus of elasticity that is less than 100 MegaPascals and greater

than about 0.1 MegaPascals, and an ultimate tensile strength that is greater than about 100

kiloPascals.

64. (New) A spinal disc prosthesis according to Claim 63, wherein the unitary body

has compressive modulus of elasticity that is between about 0.1 MegaPascal to about 10

MegaPascals.

65. (New) A spinal disc prosthesis according to Claim 64, wherein the unitary body

has an ultimate stretch in at least one direction of at least about 15%.

66. (New) A spinal disc prosthesis according to Claim 63, wherein the body is

unbounded on upper and lower surfaces to allow for axial expansion of about 20% when

placed in a Normal saline solution for about 24 hours.

67. (New) A spinal disc prosthesis according to Claim 63, wherein the unitary body

has opposing top and bottom faces, and wherein the unitary body can withstand at least about

Application Serial No.: 10/658,932

Filed: September 9, 2003

Page 11 of 14

2 degrees of rotation between the top and bottom faces with torsions of at least about 0.1 N-m

without failing.

68. (New) A spinal disc prosthesis according to Claim 67, wherein the unitary body

can withstand between about 2 degrees to at least about 10 degrees of rotation between the

top and bottom faces with torsions between about 0.1 N-m to about 1 N-m without failing.

69. (New) A spinal disc prosthesis according to Claim 63, further comprising a non-

metallic mesh sleeve on an axially extending surface thereof.

70. (New) A spinal disc prosthesis according to Claim 63, wherein the unitary body

has anisotropic elasticity.

71. (New) A spinal disc prosthesis according to Claim 63, further comprising a

plurality of axially extending tabs of that are attached to the unitary body and extend beyond

upper and lower bounds of the unitary body in the axial direction.